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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/750,990	12/28/2000	Jorn Borch Soe	674509-2028	9458

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EXAMINER

HENDRICKS, KEITH D

ART UNIT PAPER NUMBER

1761

DATE MAILED: 10/22/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No. 09/750,990	Applicant(s) SOE, JORN BORCH	
Examiner Keith Hendricks	Art Unit 1761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 29 July 2002.
- 2a) This action is FINAL.
- 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 44-69 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 44-69 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 - 1. Certified copies of the priority documents have been received.
 - 2. Certified copies of the priority documents have been received in Application No. _____.
 - 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8.
- 4) Interview Summary (PTO-413) Paper No(s). _____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other:

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DETAILED ACTION

Claim Rejections - 35 USC § 112

i) The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 44-46 and 48-69 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the use of lipases and/or esterases, does not reasonably provide enablement for the use of *any* random enzyme. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Applicant's arguments filed July 29, 2002 have been fully considered but they are not persuasive. At page 7 of the response, applicant states that the skilled artisan could easily use known techniques for isolating enzymes, and could refer to the "guidance as to the preferred sources for isolating such enzymes" and "the type of enzyme preferred" in the specification. This is not deemed persuasive for the reasons of record. Initially, it is noted that applicant's reference to the specification, as example of support of the instant claims, is on target with the very rejection attempted to be rebutted. The rejection states that "the specification, while being enabling for the use of lipases and/or esterases, does not reasonably provide enablement for the use of *any* random enzyme." Therefore, applicant's statement that the specification provides for the use of certain types of enzymes, is not argued, but is not deemed persuasive to overcome the actual rejection at hand. Applicant has not addressed the specific points raised in the rejection of record, which applied the principles for the assessment of proper enablement. Applicant's claim language is unduly broad, presumably in an attempt to gain as much patent coverage as possible; however, this does not serve to clearly and distinctly point out applicant's invention, nor does it serve to provide the required enablement under this statute. If applicant were to argue that the current claim language somehow only encompassed lipase or esterase enzymes, then (a) this is not clear from the record, and (b) it is unclear as to why applicant does not simply and clearly claim such, without inviting the present rejection and issues. Regardless, the claims would still require one skilled in the art to experiment an unduly broad range of enzymes, in order to find one(s) that provided the recited activity. Simply reciting an enzymatic activity does not, *per se*, provide sufficient guidance to actually search,

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locate, assay, determine, isolate and utilize a specific enzyme with this activity, from any particular source, of any random class of enzymes.

- ii) The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 44-69 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant's arguments filed July 29, 2002 have been fully considered but they are not persuasive.

- A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949).

In the present instance, the claims recite the broad recitation of "esterase", and the claim also recites a "lipase", which is the narrower statement of the range/limitation. As a lipase *is* an esterase, it is unclear as to what enzymes are intended to be encompassed by the limitation(s) recited.

(Note that, similarly, the phrase "a constituent comprising a hydroxy group" conflicts with "alcohols", and other constituents recited in claim 52. Similarly, in claim 59, peptides are defined by the specification as "partly hydrolysed protein", thus overlapping, wholly or completely, with "protein hydrolysates".)

At page 8 of the response, applicant states that "not all lipases have such esterase activity, thereby preventing 'lipase' from being considered part of the range 'esterase'." This is not deemed persuasive for the reasons of record. The Examiner is unaware of any lipase that is not an esterase, as lipases are specifically classified in the general "esterase" grouping of enzymes. Lipases have the enzyme classification assignment of EC# 3.1.1+, which clearly, distinctly and solely falls under the esterases, which are classified under EC# 3.1+, as acting on ester bonds. For lipases, see pages 306-315 of "Enzyme Nomenclature", 1992, the art-accepted definitive reference guide to enzyme classification, and

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see pages 306-345 for esterases. Applicant has provided no basis for their conclusion. The rejection stands for the reasons of record.

- It remains unclear as to what is encompassed by a "derivative" of one of the enzymes. At page 9 of the response, applicant states that the term would be known to encompass "simple chemical variations, which may or may not alter the function of the enzyme, functional derivatives and recombinant enzymes with natural or non-natural mutations." This is precisely the issue raised by the examiner, as this does not serve to clearly and distinctly define the term. It encompasses non-functional "derivative", so much so that they would hardly resemble the original enzyme, if at all (for example, it is unclear if a single amino acid would be considered a "derivative"). Further, as previously stated, recombinant and/or natural mutations, are not typically considered to be "derivatives" of enzymes, and therefore it is unclear as to how applicant has arrived at their conclusion without any supportive basis in the art or specification. Applicant may not add material to the originally filed specification.
- Similarly, it remains unclear as to what is encompassed by the term "derivative" as used in claims 52 and 59 (formerly claims 36-37).
- The limitations of claim 59 (formerly claim 37) remain unclear. The distinction between "protein hydrolysates" and "peptides", is not provided. Peptides are defined by the specification as "partly hydrolysed protein", thus overlapping, wholly or completely, with "protein hydrolysates".
- The term "spreads", in claim 67 (formerly claim 38), is indefinite. At page 9 of the response, applicant states that spreads 'officially' fall into one of three categories of "spreadable fats", and that "margarine is specifically defined in fat group B, but somehow continues on to argue that "it is clear that 'margarine'... is not a subset of 'spreads'." This is not deemed persuasive for the reasons of record. Given applicant's own admission, margarine is, indeed, a subset of "spreads", as would be mayonnaise, as previously stated. Thus and again, it is unclear as to what types of foodstuffs are encompassed by the term, and what would qualify as a "spread". Further, it is apparent that certain other foodstuffs recited in the claim would be considered "spreads", such as margarine, whipped cream and mayonnaise, and thus this presents a situation similar to that for

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“enzymes” and “lipases”, as discussed above. Thus, in the present instance, the claims recite the broad recitation of “spreads”, and the claims (67-68) also recite margarines, whipped cream and mayonnaise, which are the narrower statements of the range/limitation.

- It remains unclear for what function the “second functional ingredient” is used. It is unclear if this is a by-product of the reaction, for example, water, and/or if this is a compound which is material to the foodstuff. At page 10 of the response, applicant states that “the term ‘functional ingredient’ is defined [in the specification] as a constituent of the foodstuff which performs a specific function in the foodstuff.” This definition is circular and does not help further clarify the issue. Broadly-recited exemplary preferences of types of “functional ingredients” do not serve to clarify the issue, nor do they serve to provide an understanding of the fundamental properties of a “functional ingredient.”

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

1. Claims 44-53 and 60-69 are rejected under 35 U.S.C. 102(b) as being anticipated by Van Den Ouweland et al. (US PAT 5,695,802, of record). The reference is taken as cited in a previous Office action.

Applicant's arguments filed July 29, 2002 have been fully considered but they are not persuasive. At pages 11-12 of the response, applicant states that the reference “does not disclose or suggest the presence

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of a second constituent in the food material, nor the generation of a second functional ingredient from a second constituent." This is not deemed persuasive for the reasons of record.

Applicant's argument provides support and rationale for the rejections under 35 USC 112 2nd paragraph, above. Applicant may not summarily dismiss the reference, simply because it does not broadly refer to a "second constituent" or "second functional ingredient", *per se*. These terms broadly encompass thousands of compounds, several of which are found in the foodstuffs of the reference. Further, the specific foodstuffs of the reference are both broadly and specifically recited by the instant claims (butter and oil), and thus as previously stated, absent any clear and convincing evidence and/or arguments to the contrary, as the method steps are the same as those instantly claimed, and the claim limitations encompass the teachings of the reference, it would be expected that the same enzymatic reaction(s) would yield "an emulsifier" compound, as well as a by-product secondary compound(s).

2. Claims 44-69 are rejected under 35 U.S.C. 102(e) as being anticipated by Michelsen et al. (US PAT 6,143,543). The reference is taken as cited in a previous Office action.

Applicant's arguments filed July 29, 2002 have been fully considered but they are not persuasive. At page 12 of the response, applicant states that the reference mistakenly recites "glyceride oligomers", instead of "glucoside oligomers"; that the reference does not teach or suggest the generation of an emulsifier; and that the foodstuff of the reference does not comprise fatty acid esters. This is not deemed persuasive for the reasons of record.

Again, Michelsen et al. provides an enzyme system comprising a ferulic acid esterase (FAE) from *Aspergillus niger*, which "can improve food and feed and the preparation of food and feed" (col. 2). The reference specifically demonstrates the use of the esterase upon plant material, such as wheat (bran, or water insoluble pentosans), sugar beets, and corn. Further, the enzyme is used within a method to form a dough and bakery products (col. 5. See also examples G-H.). At col. 7, lines 44-47, it is stated that the enzyme substrates may include polysaccharide-based substrates such as xylan and pectin, as well as "glyceride oligomers". Applicant has provided no further basis to their conclusion that the production of "glyceride oligomers" is a typographical error, especially given the specific type of esterase and foodstuff of the reference. Further, applicant's claims in no way are limited to this extent, especially given the broad, indefinite terms "functional constituent" and "functional ingredient".

As previously stated, example G of the reference demonstrates the use of the enzyme, with water, upon wheat bran, whereupon completion, the reaction was stopped by freeze drying, thus inactivating the enzyme. Whether or not "the effects of freeze-drying the enzyme are temporary", as applicant purports,

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this does not detract from the inactive status of the enzyme when freeze-dried. Further and again, wheat naturally contains various glyceride compounds, including triglycerides. Wheat also contains various mono- and poly-saccharides, i.e. sugars, such as xylose, glucose, fructose. Similarly, corn naturally contains triglycerides (for example, in corn oil) and sugars (for example, corn syrup), as well. Thus, the reference teaches the addition of an *Aspergillus niger* esterase to "a food material containing a triglyceride". As the method steps are the same as those instantly claimed, and the claim limitations encompass the teachings of the reference, it would be expected that the same enzymatic reaction(s) would yield "an emulsifier" compound, as well as a by-product secondary compound(s).

3. Claims 44-53 and 60-69 are rejected under 35 U.S.C. 102(b) as being anticipated by Moore et al. (EP 0 652 289, of record). The reference is taken as cited in a previous Office action.

Applicant's arguments filed July 29, 2002 have been fully considered but they are not persuasive.

With regard to Moore et al., applicant states that, because the referenced section under "lipolysis" teaches "washings to remove free fatty acids and partial glycerides", then the remaining sample cannot contain a "second constituent." This is not deemed persuasive for the reasons of record. Simply because free fatty acids and partial glycerides are removed, does not then imply that only triglycerides remain, with no "secondary constituent." In fact, at column 6, lines 5-11, the reference states that the remaining sample is placed in a sonic bath "to ensure complete emulsification." This would not be possible without an *emulsifier* naturally present in the foodstuff. Thus and again, as the method steps are the same as those instantly claimed, and the claim limitations encompass the teachings of the reference, it would be expected that the same enzymatic reaction(s) would yield "an emulsifier" compound, as well as a by-product secondary compound(s).

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Conclusion

Regarding applicant's comment at page 14 of the response, applicant is entitled to call the undersigned if they wish to arrange an interview to discuss the merits of the claimed invention and the instant rejections.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Keith Hendricks whose telephone number is (703) 308-2959. The examiner can normally be reached on M-F (8:30am-6pm); First Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Milton Cano can be reached on (703) 308-3959. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3602 for regular communications and (703) 872-9565 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.


KEITH HENDRICKS
PRIMARY EXAMINER